Award Number: **W81XWH-11-2-0129**

TITLE: **PHIT for Duty, a Personal Health Intervention Tool for Psychological Health and Traumatic Brain Injury**

PRINCIPAL INVESTIGATOR: **Paul N. Kizakevich, M.S., P.E.**

CONTRACTING ORGANIZATION: **RTI International**
North Carolina 27709

REPORT DATE: **April 2015**

TYPE OF REPORT: **Annual**

PREPARED FOR: **U.S. Army Medical Research and Materiel Command**
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: **Approved for Public Release; Distribution Unlimited**

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
April 2015	ANNUAL	15 Mar 2014 - 14 Mar 2015

4. TITLE AND SUBTITLE	5a. CONTRACT NUMBER
PHIT for Duty, a Personal Health Intervention Tool for Psychological Health and Traumatic Brain Injury	W81XWH-11-2-0129
	5b. GRANT NUMBER
	5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)	5d. PROJECT NUMBER
Paul N. Kizakevich	5e. TASK NUMBER
E-Mail: kiz@rti.org	5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)	8. PERFORMING ORGANIZATION REPORT NUMBER
Research Triangle Institute 3040 Cornwallis Road Research Triangle Park, NC 27709-2194	

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)	10. SPONSOR/MONITOR'S ACRONYM(S)
U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012	
	11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The purpose of this project is to help prevent psychological disorders in high-risk individuals with early symptoms of stress, depression, substance use, and other health problems. PHIT for Duty integrates self-report and physiological sensor instruments to assess health status via brief weekly screening questionnaires in five domains (i.e., stress, anxiety, sleep quality, depression, and alcohol use). An expert system, called the intelligent virtual advisor (iVA), processes these data using evidence-based logic to determine health risk and to prescribe SHIs including mindfulness meditation, health education, and cognitive behavior change modules for reducing stress, attentional restructuring, improving sleep and reducing alcohol use. Persons with high risk are advised to consult their primary care provider for a professional health assessment. Persons with mild or moderate risk (i.e., subclinical scores), are presented with a suite of interventional, therapeutic, and monitoring activities to support post-traumatic stress reduction. These include skills acquisitions (e.g., mindfulness meditation), health education (e.g., sleep hygiene), cognitive behavior change (i.e., alcohol use lessons), and self-monitoring activities (e.g., alcohol use diary). A "to-do" list of assessments and activities is updated daily and displayed on the PHIT for Duty home screen as a menu for the user. Usability evaluation of the PHIT for Duty health assessments, physiological sensors , system acceptability, and overall system functionality have shown positive results and affirmation of the PHIT mobile application framework design.

15. SUBJECT TERMS

PTSD, post-traumatic stress disorder, mobile health, smartphone, self-help, iOS, Android

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE			
U	U	U	UU	12	19b. TELEPHONE NUMBER *(include area code)*

Table of Contents

Section   Page

1. INTRODUCTION

The goal of this project is to support prevention of psychological health problems and post-traumatic stress disorder (PTSD) through innovation in mobile personal health assessment and self-help intervention (SHI).

Our objective is to develop and evaluate PHIT for Duty, a field-deployable personal device to help build resilience in healthy troops and support prevention in high-risk personnel. Based on RTI's Personal Health Intervention Tool (PHIT) platform, PHIT for Duty will integrate a suite of health assessments with an intelligent virtual advisor (iVA) that recommends, tailors, and presents self-help advisories based on established rules and processes. The PHIT platform will comprise a smartphone or tablet and optional, nonintrusive physiological and behavioral sensors for health status monitoring and intervention.

PHIT for Duty is intended to be used for secondary prevention of psychological health problems in persons who have been exposed to psychological trauma and may be having some symptoms of distress, but have not been diagnosed with any psychological disease or disorder. PHIT for Duty, however, may eventually prove useful as a treatment option, and therefore should be developed according to good software development practices.

The project comprises (1) formative research to identify psychological assessments and SHIs to assist individuals in dealing with combat and operational stress and the psychological and physiological consequences of that exposure; (2) development of personal, mobile technologies for longitudinal health assessment and SHI; (3) testing, refinement, and validation of PHIT for Duty technologies through beta testing and pilot studies; (4) evaluation the efficacy of the PHIT methodology for prevention in a randomized controlled trial (RCT) with post-deployed personnel; and (5) adapting the developed system for several popular smartphone or tablet computer platforms, including both Google Android™ and Apple iOS based devices.

2. BODY

2.1. Task 1: Concept formation and development planning

No work on this task was performed this year.

2.2. Task 2: Prototype design and development

2.2.1. The Personal Health Information Tool architecture

The PHIT platform is a mobile application framework that integrates multimodal data collection with an intelligent virtual advisor that analyzes real-time data to recommend, tailor, and present domain-specific activities based on established rules and scripted processes (**Exhibit 1**). PHIT facilitates building complex smartphone/ tablet applications with both self-entry and autonomous sensor-based instruments. Objective data are acquired via cognitive tests, interactive exercises, serious games, and various Bluetooth sensors. Periodic assessments of various domains are analyzed to instruct users and recommend activities tailored to the scope of the application. All acquired data are stored on the mobile device using an encrypted database, periodically uploaded to a secure server, and made available for quality review and analysis via a password-protected website.
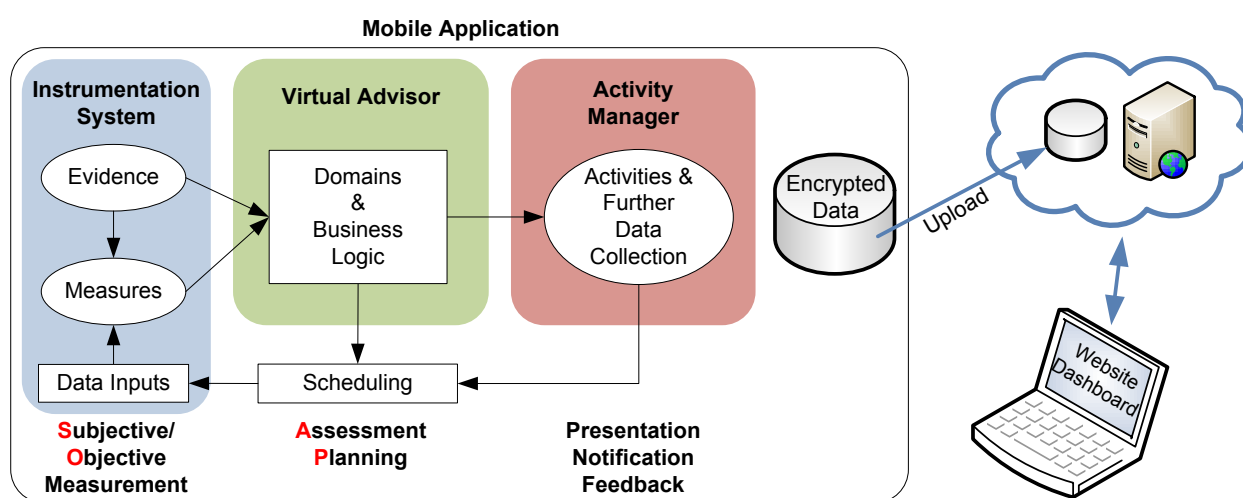

Exhibit 1. PHIT mobile application framework architecture.

2.2.2. The PHIT for Duty mobile health application

The PHIT for Duty application comprises a variety of subjective and objective data collection instruments, interactive self-help activities, health information, personal feedback, and other presentation modules (**Exhibit 2**). Required user actions, like completing a brief morning sleep quality questionnaire, are managed via a task menu screen. The task list is updated each day according to logic rules managed via the intelligent virtual advisor.

At baseline, personal, psychological, social, and combat history data are collected.   Then, on a periodic basis (e.g., bi-weekly), health status is assess via brief screening questionnaires in five domains (i.e., stress, anxiety, sleep quality, depression, and alcohol use). For each domain, the screening data are analyzed and a subsequent assessment is given should the screener score meet certain criteria. Any such detailed assessment is categorized by none, mild, moderate, or likely risk of disease for that domain.

Persons with likely risk are advised to consult their primary care provider for a professional health assessment. Persons with mild or moderate risk (i.e., subclinical scores), are presented with a suite of interventional, therapeutic, and monitoring activities to support post-traumatic stress reduction. These include health management information (i.e., cognitive lessons), skills acquisitions (e.g., meditation, muscle relaxation), tools (e.g., sleep hygiene checklist), and self-monitoring activities (e.g., alcohol use diary). All of these screening instruments, assessment instruments, and self-help interventional activities, as well as the iVA health management expert system, are components of the PHIT for Duty smartphone/tablet mobile application. The "to-do" list of assessments and activities to be performed by the user is updated daily and displayed on the PHIT for Duty task list screen.
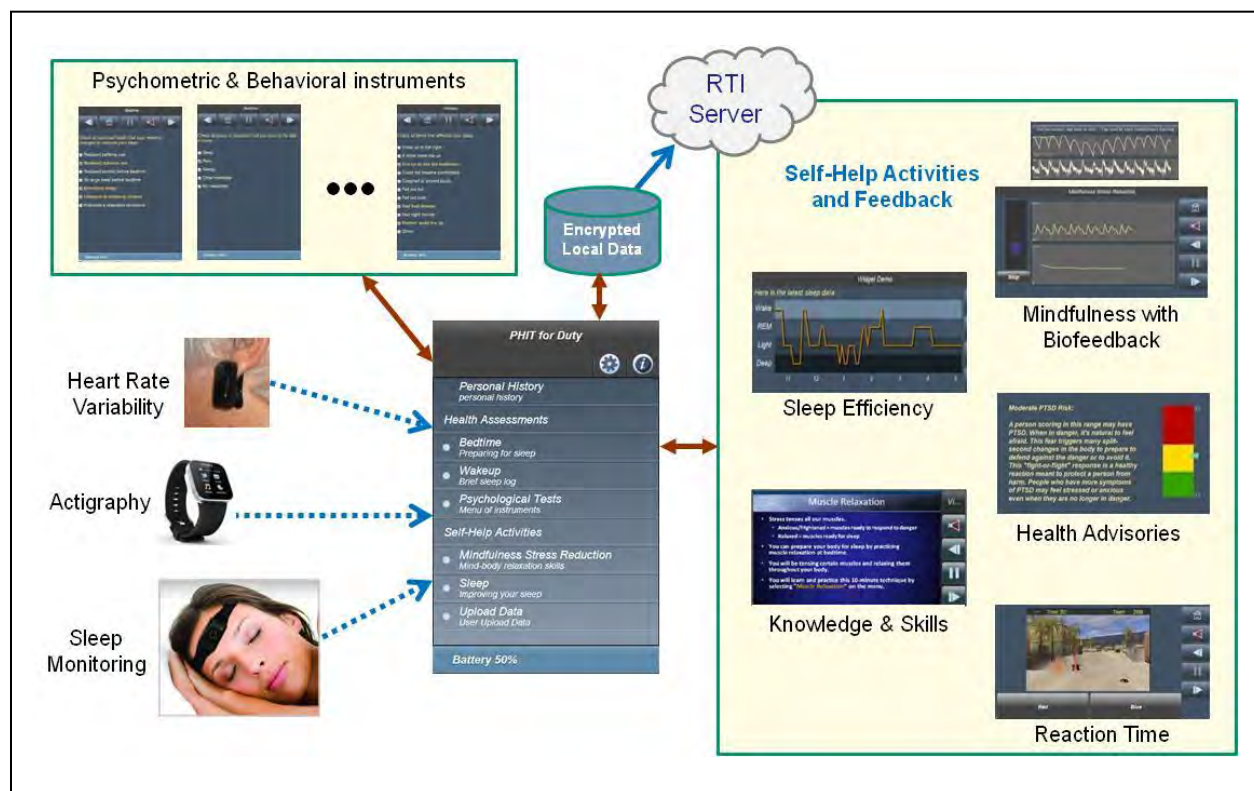
Exhibit 2. Representative data collection instruments, user task menu, self-help activities, and health information feedback modules in the PHIT for Duty application.

The primary activity in Task 2 was the continued iterative testing, evaluation, and updating of the application functionality to prepare the system for pilot testing at Fort Bragg. Wanting to ensure that the soldiers would not run into any problems with the app, and that the acquired data would be accurate, we performed the following testing activities:

- Each of the health assessment and health intervention modules were executed by RTI software quality assurance staff, and feedback was provided to the programmers on usability, spelling errors, grammatical errors, screen layout problems, and form navigation issues

- The PI executed all of the assessment modules multiple times with varying simulated data entries, noting the entries, and then checking that the entered data were accurately records and uploaded to the PHIT research database.

- All of the intermediate and final assessment scores were calculated manually and then compared with the automated calculations to verify accuracy. There were also checked against the values that were uploaded to the PHIT research database.

- Any identified errors in spelling, syntax, or calculation were corrected in the PHIT XML code, and the testing process repeated to check that the repairs were correct.

Considering that the assessments and interventions will be performed over a 4-6 week period, we modified the PHIT application clock to allow for "time warping", via a virtual clock. Rather than to use the system clock for application task timing, we implemented a virtual clock which can be sped up or slowed down relative to real time (the system clock). We could also advance each virtual day manually by adding 24 hours to the virtual clock under software control. This method permit us to quickly step through a multiple-day protocol, thereby allowing complete testing of the pilot study (30 days) in just a few hours. However, to ensure that the system will work as required in real time, we also had to carry out multiple pilot study simulations of 30-days each for validation of the protocol timing. These tests occupied much of the first 4 or 5 months of the project year.

2.3. Task 3: Beta testing in civilians

No additional beta testing was performed this year.

2.4. Task 4: Pilot study in service members

2.4.1. Recruitment and Study Execution

The pilot study protocol was initially approved by Research Triangle Institute (RTI) in October of 2012. Since then there have been a series of issues which have delayed startup and a successful implementation of the study.

In July 2013, Dr. Mary Lela Demby, Lieutenant Commander (O-4), US Public Health Service and Clinical Psychologist, agreed to serve as principal investigator at Womack Army Medical Center (WAMC) and began working with us to submit the protocol to the WAMC IRB. After several rounds of revisions, the WAMC IRB approved the protocol on 14 March 2014 and subsequently the RTI IRB on 24 June 2014. This protocol was reviewed by the US Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) and

found to comply with applicable DOD, US Army, and USAMRMC human subjects protection requirements. An approval memorandum was received from the HRPO on 24 July 2014.

We began recruitment in late July with a posting on Craig's List and a 1/4 page advertisement in the Fort Bragg Life and Paraglide newspapers. Unfortunately we received only a few inquiries over two weeks, none of which were either interested or met qualifications.

We decided to switch to flyers and have posted them at places on Post where solders gather and have distributed them directly to individuals. This change required a protocol modification which was submitted first to the RTI IRB, and then to the WAMC IRB. These approvals took about a month. Meanwhile we hired a local person as a consultant (a veteran and whose husband is an instructor at the Special Forces School) to be our lead person for on-post recruiting and as support staff for participant interactions. She distributed nearly 300 flyers, both at the mini-mall and the Post Exchange which produced no inquiries. Several negative comments were noted, including inadequate compensation for participation ($50) for the effort required and not wanting any more "PTSD studies" in general.

We were concerned that the "returned from deployment within 12 months" inclusion criterion, may be limiting so we decided to drop that criteria since deployment cycles have been greatly reduced in recent years. Of course that meant going back again to both the RTI IRB and the WAMC IRB for approval of the protocol modification, and additional delay before we might resume recruitment. Approval for this modification was received from the RTI IRB on 22 September, submitted to the WAMC IRB on 22 October, and approved on 5 November 2014.

Recruitment resumed again via flyer distribution and other means, and prospective participants finally started responding to the recruitment ads. Twenty persons responded to the ads during this year, and another four early of the next year (after March 14, 2015).

Of these, only two had met our inclusion criteria:

- ID #201 was trained on 3/11, performed the study, and was debriefed on 4/11

- ID#202 was trained on 3/27, performed the study, and was debriefed on 4/28.

The responded that did not meet inclusion/exclusion criteria were as follows

- Seven had PTSD scores below the minimum criteria

- Fourteen had ever been diagnosed for PTSD, anxiety, depression, or mental health condition

- One was being transferred from Fort Bragg within the next week

Although prospective participants continued to respond to existing ads and flyers, active recruitment was suspended in early March due to insufficient funds. Recruitment was to be resumed pending a

revised scope of work and budget, and pending revisions in the protocol that would permit us to accept individuals who may have had a previous mental condition, but were not currently under medical care. A protocol modification to this effect is currently in review.

2.5. Task 5: Randomized controlled trial in post-deployed personnel

No work to date on this task.

2.6. Task 6: Migration to other smartphones and tablets

No work this year on this task.

3. KEY RESEARCH ACCOMPLISHMENTS

To date the main research accomplishments have been development of the PHIT mHealth platform, development of the PHIT for Duty mHealth application, and demonstration of a high level of usability in an age-appropriate civilian population.

4. REPORTABLE OUTCOMES

4.1. Manuscripts, abstracts, presentations

During the last project year, the following publications and presentations were made based on projects using either the PHIT framework or the PHIT for Duty mobile application:

Eckhoff, R. P., Kizakevich, P. N., Bakalov, V. D., Zhang, Y., Bryant, S. P., & Hobbs, M. A. (2015). A Platform to Build Mobile Health Apps: *The Personal Health Intervention Toolkit (PHIT)*. JMIR mHealth and uHealth, 3(2), e46. doi:10.2196/mhealth.4202

Kizakevich, P. N., Eckhoff, R. P., Weger, S. A., Brown, J. M., Miller, S., Weeks, A. L., Bryant, S. P., Weimer, B. J., Bakalov, V. D., Zhang, Y., Spira, J. L. (2014, October). *PHIT for Duty – A Mobile Application to Improve Psychological Health and Reduce Alcohol Use in Persons with Post-Traumatic Stress*. Presented at Medicine 2.0: Social Media, Mobile Apps, and Internet/Web 2.0 in Health, Medicine and Biomedical Research, Malaga, Spain.

Eckhoff, R. P., Kizakevich, P. N., Bakalov, V. D., Zhang, Y., Bryant, S. P., & Hobbs, M. A. (2014, November*). PHIT™ – A Personal Health Intervention Toolkit for Building Mobile Health Applications*. Presented at Medicine 2.0'14 Summit & World Congress, Maui, HI.

Kizakevich, P. N., Eckhoff, R. P., Weger, S. A., Weeks, A. L., Brown, J. M., Bryant, S. P., Bakalov, V. D., Zhang, Y., Lyden, J. T., & Spira, J. L. (2014). *A personal health information toolkit for health intervention research*. Studies in Health Technology and Informatics, 199, 35–39.

Kizakevich, P. N., Eckhoff, R. P., Zhang, Y., Bryant, S. P., Bakalov, V. D., Weger, S. A., Lyden, J. T., & Weeks, A. L. (2014, April). *PHIT for Duty™, a Mobile Health Assessment and Intervention Application for Post Traumatic Stress and Psychological Disorders.* Poster presented at mHealth@Duke, Durham, NC. Best Poster Award

During the previous project years, the following publications and presentations were made based on projects using either the PHIT framework or the PHIT for Duty mobile application:

Kizakevich, P. N., Eckhoff, R. P., Bakalov, V. D., Zhang, Y., Bryant, S. P., Lyden, J. T., Weger, S. A., Weeks, A. L., & Brown, J. M. (2013, October). *PHIT for Duty, a Mobile Health Assessment and Intervention Application for Post-Traumatic Stress and Psychological Disorders*. Poster presented at Inaugural Symposium on Using New Technologies to Enhance Healthy Behaviors, Chapel Hill, NC.

Kizakevich, P. N. (Invited Speaker). (2013, November). *Implementing PHIT, a mHealth Toolkit for Posttraumatic Stress and Health Intervention Research*. Presented at DoD/VA mHealth Summit, Arlington, VA.

Hourani, L. L., Kizakevich, P. N., Tueller, S. J., Weimer, B. J., Lewis, G. F., & Bryant, S. P. (Invited Speaker). (2013, August). *Combat Stress Casualty Reduction: Development and Testing of a Predeployment Stress Inoculation Training Program*. Presented at Military Health Services Research Symposium, Ft. Lauderdale, FL. Weger, S. A., Kizakevich, P., Eckhoff, R. P., Zhang, Y., Lyden, J. T., Bakalov, V. D., & Bryant, S. P. (2013, May). *PHIT for Duty: Exploring a mobile data collection framework*. Presented at AAPOR Annual Conference, Boston, MA.

Bagwell, J. E., Furberg, R. D., Kizakevich, P. N., Eckhoff, R. P., Zhang, Y., Bakalov, V. D., Simoni, D. A., Hobbs, C. L., & LaBresh, K. A. (2013, April). *A mobile clinical decision support tool for implementing the NHLBI Expert Panel Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents*. Poster presented at mHealth@Duke 2013, Durham, NC.

Kizakevich, P. N., Eckhoff, R. P., Lyden. J., Hubal, R, and Brown, J.. (2013, February). *PHIT for Duty™, a Mobile Health Assessment and Intervention Application for Post Traumatic Stress and Psychological Disorders*. Poster presented at Digital Health Communication Extravaganza, February 21, 2013, Orlando, FL.

Kizakevich, P. N., Hubal, R. C., Brown, J. M., Lyden, J. T., Spira, J. L., Eckhoff, R. P., Zhang, Y., Bryant, S. P., & Munoz, G. (2012). PHIT for Duty, a Mobile Approach for Psychological Health Intervention . *Studies in Health Technology and Informatics*, *181*, 268–272. doi:10.3233/978-1-61499-121-2-268

Bagwell, J. E., Furberg, R. D., Kizakevich, P. N., Eckhoff, R. P., Zhang, Y., Bakalov, V. D., Simoni, D. A., Hobbs, C. L., & LaBresh, K. A. (2013, April). *A mobile clinical decision support tool for implementing the NHLBI Expert Panel Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents*. Poster presented at mHealth@Duke 2013, Durham, NC.

Zhang, Y., Roe, D. J., Keating, M. D., Kizakevich, P. N., Eckhoff, R. P., Bryant, S. P., Munoz, G., & Hubal, R. C. (2012, May). *SurveyPulse - A Cross-Platform Mobile Survey App Created with Adobe Flex*. Presented at IFDTC, Orlando, FL.

Kizakevich, P.N. (2012, January). *Mobile technologies for health monitoring and intervention*. Invited presentation, Raleigh Engineers Club, Raleigh, NC.

Eckhoff, R.P., Kizakevich, P.N., Zhang, Y., & Hubal, R.C. (2012, February). *Personal Health Intervention Tool: A mobile framework using Adobe Flash Builder*. Poster presented at the Digital Health Communication Extravaganza, Orlando, FL.

Hubal, R. (2012, April). *The imperative for social competency prediction*. Talk presented at the Social Computing, Behavioral Modeling and Prediction Conference, College Park, MD.

4.2. Licenses applied for and/or issued

o   No patents or disclosures have been filed.

o   RTI plans to copyright the PHIT platform and PHIT for Duty source code and application.

o   The PHIT platform may be recognized as a medical device; currently an investigational device exemption has been granted by RTI's IRB.

4.3. Degrees obtained that are supported by this award

None

4.4. Development of cell lines, tissue or serum repositories

Not applicable

4.5. Infomatics such as databases and animal models

None

4.6. Funding applied for based on work supported by this award

The PHIT mobile technology framework has been instrumental in the expansion of mobile application and intervention research across a variety of health domains. The research projects listed below have made use of either the PHIT framework or the PHIT for Duty application as a key component.

Funded:

- **Pediatric CVD Risk Reduction**. A mobile clinical decision support tool for implementing the NHLBI Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescent. National Heart, Lung, and Blood Institute, Dr. Ken LaBresh, PI.
  Available on Apple and Google App stores.

- **Flight Attendant Wellness**. PHIT-based substance abuse reduction in flight attendants Substance and Mental Health Services Administration, P. Kizakevich (PI).
  Available on Apple and Google App stores.

- **ActiSleep.** PHIT-based sleep diary for data collection in an adolescent sleep and marijuana study. National Institute on Drug Abuse, Dr. D. Fishbein, PI

- **Adaption of Mindfulness Training to Treat Chronic Pain in the Military**
  National Center for Complementary and Alternative Medicine, Dr. S. Miller, PI

- **Mocha.** PHIT-based monitoring outcomes for change in fragile X syndrome children. Robert Furberg and Anne Wheeler (PIs). RTI IRAD award.

- **Obesity Study.** PHIT-based data collection for diet and activity monitoring.
   NIH. Vanessa Duren-Winfield, PhD, (PI). Winston-Salem State Univerasity

Pending award or in review:

- **PocketLab.** PHIT-based asthma and environmental monitoring in children. Paul N. Kizakevich, MS, PE (PI). NIH.

- **Women's Co-**op. PHIT-based HIV/AIDS and substance abuse health education for youg women at risk. NIH (highly ranked review score at 14)

- **myPAL.** PHIT-based emotion and behavior regulation for adolescents with high functioning autism. Paul N. Kizakevich, MS, PE (PI). CDMRP.

- **PHIT for Living.** PHIT-based transitions to independence for individuals living with ASD. Anne Wheeler, PhD (PI). CDMRP.

4.7. Employment or research opportunities applied for and/or received based on experience/training supported by this award

See section 4.5.

5. REFERENCES

None.